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10/660,429	09/12/2003	Michael F. Harris	HAR-001	4876

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EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,429	HARRIS, MICHAEL F.	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *WO 96/31217*.

DETAILED ACTION

This Action is in response to the amendment filed on 5/8/2008. Claims 1 and 9 were amended, claims 2 and 3 were cancelled, and claims 19 and 20 were added. Currently, claims 1, 3-9, and 11-20 are pending in the instant application.

Claim Objections

Claim 14 is objected to because of the following informalities: in line 3, it appears "ata" should be changed to --atm-- to correct a typographical mistake. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9, 11-14, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, in line 3 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 1 and 9, in lines 6 and 9, respectively, the limitation "wherein the one or more gases, except for air, make up 5% or more of the gases" is somewhat unclear because the examiner is unsure whether the air is referring back to the "surface air" that was previously

claimed. In addition, if the surface air is being referred back to, how could it not make up 5% or more of the gases because it appears that when surface air is being used in hyperbaric chambers that it makes up 100% of the gases.

Claims 3-8 and 19 are dependent on claim 1 and are therefore rejected for the reasons outlined above with respect to claim 1.

Claims 11-14 and 20 are dependent on claim 9 and are therefore rejected for the reasons outlined above with respect to claim 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watt (US 4,554,9616).

Regarding claims 15 and 16,Watt discloses a therapeutic inhaler for the delivery of nitrous oxide at atmospheric pressure (see abstract). Watt does not disclose that the device is used for treating virus or HIV. However, the method steps would have directly resulted from use of the device (i.e., upon inhalation of the nitrous oxide, viruses within the patient's body would be treated). The mechanisms by which the virus is treated (i.e., inhaled nitrogen blocking virus-host attachment sites to prevent replication) are inherently carried out by the patient inhaling the nitrous oxide. To the extent, if any, that Watt is silent as to selecting an inhalation period and

time and repeating the step of inhaling, examiner contends that is would have been obvious to one of ordinary skill in the art at the time of the invention to have had a patient breath the nitrous oxide for repeated periods of time that may or may not differ in order to effectively treat the patient by supplying enough of the nitrous oxide for therapy. In addition, this practice is well known and commonly used in inhalation therapy so it appears as though the device of Watt would work equally well with a patient inhaling the nitrous oxide for repeated time periods. However, examiner notes that it appears as though any amount of time a patient breathes the nitrous oxide could be broken down into an arbitrary "inhalation period" (i.e., if a patient breathes nitrous oxide for 6 minutes, one could say the inhalation period is 1 minute, followed by an inhalation period of 2 minutes and that the step is repeated 2 times, for example).

Regarding claims 17 and 18, Watt does not disclose that the nitrous oxide is provided at a concentration of 5% or more or that different percentages of nitrous oxide are used in different inhalation periods but rather that the nitrous oxide concentration can be varied and must be mixed with at least some oxygen or air so that the gas is not lethal to a human. Therefore, examiner contends it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the nitrous oxide in the device of Watt in varying amounts for different therapies or as a patient's condition improves and at an optimal concentration of at least 5% so that there is enough nitrous oxide circulating in the patient to effectively treat the patient.

Claims 1, 4, 6-9, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamow et al. (US 4,974,829).

Regarding claims 1, 4, 6, 9, 11, 19, and 20, Gamow et al. discloses a hyperbaric chamber that exposes an individual to surface air at pressures from 0-10 lbs/square inch above atmosphere (abstract and column 4, lines 1-10). The device also monitors vital signs (column 4, lines 34-35) and can be used daily for different amounts of time (column 4, lines 39-42). The number of days the treatment is carried out is considered an obvious design consideration to one of ordinary skill in the art depending on the condition of the patient. The difference between the instant claims and Gamow et al. is that Gamow et al. does not disclose that the device is used for treating viruses or HIV. However, the method steps would have directly resulted from use of the device (i.e., upon inhalation of the air within the chamber, viruses within the patient's body would be treated). The mechanisms by which the virus is treated (i.e., inhaled nitrogen blocking virus-host attachment sites to prevent replication) are inherently carried out by the patient inhaling the surface air.

Regarding claim 7, Gamow et al. is silent as to creating an exposure chart. However, absent a critical teaching and/or a showing of unexpected results from creating an exposure chart, examiner contends it is an obvious design consideration to one of ordinary skill in the art to create an exposure chart in order to keep track of the patient's condition and to monitor the effectiveness of therapy. In addition, charts are well known and commonly used in the art and it appears as though the device of Gamow et al. would perform equally well with an exposure chart.

Regarding claims 8 and 13, the hyperbaric chamber of Gamow et al. is large enough to fit more than one person (column 4, lines 25-30). Therefore, it would have been obvious to one of

ordinary skill in the art t the time of the invention to have placed more than one person in the chamber is order to treat more than one person at the same time or as a "coach".

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke University (WO 96/31217, herein referred to as Duke).

Regarding claims 15 and 16, Duke discloses a method for treating patients infected with a virus, including HIV (see page 4, 3rd full paragraph) involving the inhalation of nitric oxide (NO) at normal atmosphere pressure (see page 6, 2nd full paragraph. page 15, last paragraph, page 18, 3rd full paragraph, page 20, 2nd full paragraph, and claims 1-3). The mechanisms by which the virus is treated (i.e., inhaled nitrogen blocking virus-host attachment sites to prevent replication) are inherently carried out by the patient inhaling the nitric oxide. To the extent, if any, that Duke is silent as to selecting an inhalation period and time and repeating the step of inhaling, examiner contends that is would have been obvious to one of ordinary skill in the art at the time of the invention to have had a patient breath the nitric oxide for repeated periods of time that may or may not differ in order to effectively treat the patient by supplying enough of the NO to inhibit retroviral replication. In addition, this practice is well known and commonly used in inhalation therapy so it appears as though the method of Duke would work equally well with a patient inhaling the NO for repeated time periods (see also page 20, line 19, in which Duke discloses "frequency of treatment"). However, examiner notes that it appears as though any amount of time a patient breathes the nitric oxide could be broken down into an arbitrary "inhalation period" (i.e., if a patient breathes NO for 6 minutes, one could say the inhalation period is 1

minute, followed by an inhalation period of 2 minutes and that the step is repeated 2 times, for example).

Regarding claims 17 and 18, Duke does not disclose that the NO is provided at a concentration of 5% or more or that different percentages of NO are used in different inhalation periods. However, Duke does disclose that the "therapeutically effective amount" of NO is varied according to individual needs (see page 20). Therefore, examiner contends it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the NO in the method of Duke in varying amounts for different therapies (i.e., as the virus is slowly inhibited or eliminated from the patient, for example) and at an optimal concentration of at least 5% so that there is enough NO circulating in the patient to effectively inhibit the retroviral replication.

Claims 3, 5, 12, and14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamow et al. as applied to claims 1, 4, 6-9, 11, and 13 above and further in view of Lasley (US 4,448,189).

Regarding claims 3, 5, and 12, Gamow et al. does not disclose the claimed pressures. However, Lasley discloses a hyperbaric chamber that exposes patient with pressures of 30-70 psi, which overlaps the claimed range. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have exposed patients in the device of Gamow et al. to pressures of 30-70 psi as taught by Lasley in order to treat a given condition and to suit an individuals needs. Furthermore, it appears as though the device of Gamow et al. would work equally well if the patient were exposed to pressures of 30-70 psi.

Regarding claim 14, to the extent, if any, that Gamow et al. does not disclose decompressions intervals and choosing a decompression time off of a standard decompression table, Lasley is cited to show that it is well known to cycle patients through periods of decompression during hyperbaric therapy. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have chosen decompression times off of a standard table to ensure that the patient is not hurt. Furthermore, decompression times and tables are well known and commonly used and it appears as though the device of Gamow et al. would perform equally well if the patient were cycled through decompression times chosen from a standard table.

Claims 1, 3-9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke in view of Reillo et al. (Journal of Association of Nurses in AIDS Jan-Feb 1996) and Lasley (US 4,448,189).

Regarding claims 1, 4, 9, and 11, Duke discloses a method of treated HIV involving a patient inhaling NO but is silent as to a hyperbaric chamber. However, Reillo et al. discloses, in a method for treated HIV, placing a patient in a hyperbaric chamber for inhalation therapy. It would have been obvious to one of ordinary skill in the art at the time of the invention to have had the patient of Duke inhale NO while in a hyperbaric chamber as taught by Reillo et al. in order to provide the well known benefits of treating HIV patients with gas at an elevated pressure in a hyperbaric chamber. Furthermore, it appears as though the method of Duke would work equally well if the gas were supplied at an elevated pressure within a hyperbaric chamber inasmuch as a therapeutically effective amount were being delivered (see discussion above with

respect to the concentration of NO being greater than 5%). The individually claimed mechanisms by which the virus is treated (i.e., reducing viral load, increasing CD4/CD8 lymphocytes, blocking virus-host attachment sites to prevent replication, etc.) are inherently carried out by the patient inhaling the nitric oxide.

In addition, Reillo et al. is silent as to selecting one or more time periods for exposing the patient to the selected gases and pressure. However, Lasley discloses a hyperbaric chamber used for therapy that allows a physician to select a desired prescribed pressure and time for cycling through periods of elevated and atmospheric pressure (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the NO in the modified Duke reference with the hyperbaric chamber disclosed by Lasley in order to allow a physician to select a desired time and pressure for providing hyperbaric therapy in cycles, as is well known and commonly performed in the art.

Regarding claims 3, 5, and 12, Lasley discloses providing the pressures at 30-70 psi, which overlaps the claimed ranges. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the NO in the modified Duke device at a pressure of 30-70 psi so that the patient would receive the benefits of the elevated pressure hyperbaric therapy. In addition, these pressures are well known and commonly used in the art and it appears as though the modified Duke reference would perform equally well if the NO were provided at 30-70 psi.

Regarding claim 6, the modified Duke reference discloses that treatment is repeated (i.e., "frequency of treatment" on page 20 of Duke) but is silent as to the exposure being repeated daily for 3-21 days. Absent a critical teaching and/or a showing of unexpected results from

exposing the patient daily for 3-21 days, examiner contends it is an obvious design consideration to one of ordinary skill in the art at the time of the invention to expose the patient in the modified Duke reference to the NO daily for 3-21 days in order to effectively treat the HIV. In addition, it appears as though the modified Duke method would work equally well if repeated daily for 3-21 days and the length of treatment would depend on an individuals needs (i.e., age, weight, gender, stage of infection, etc.).

Regarding claim 7, the modified Duke reference is silent as to creating an exposure chart. However, absent a critical teaching and/or a showing of unexpected results from creating an exposure chart, examiner contends it is an obvious design consideration to one of ordinary skill in the art to create an exposure chart in order to keep track of the patient's condition and to monitor the effectiveness of therapy. In addition, charts are well known and commonly used in the art and it appears as though the modified Duke reference would perform equally well with an exposure chart.

Regarding claims 8 and 13, the hyperbaric chamber of the modified reference is large enough to fit more than one person. Therefore, it would have been obvious to one of ordinary skill in the art t the time of the invention to have placed more than one person in the chamber is order to treat more than one person at the same time.

Regarding claim 14, the modified reference is silent as to the decompression times being selected based off of a decompression table. However, absent a critical teaching and/or a showing of unexpected results from the physician selecting the cycling times from a decompression table, examiner contends it would have been obvious to one of ordinary skill in the art at the time of the invention to have elected the decompression times from a

decompression table in order to avoid hurting the patient by decompressing too quickly. In addition, decompression tables are well known and commonly used in the art at it appears as though the modified Duke reference would work equally well with a decompression table.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke, Reillo et al. and Lasley as applied to claims 1, 3-9, and 11-14 above and further in view of Gamow et al. The modified Duke reference is silent as to supplying the gas at atmospheric pressure. However, Gamow et al. discloses a hyperbaric chamber that exposes a patient to gas at atmospheric pressure (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the pressure of NO in the modified Duke reference at atmospheric pressure as taught by Gamow et al. depending on the desired treatment and pressures needed to effective treat the patient. In addition, it appears as though the modified Duke reference would perform equally well with the pressure provided at atmospheric inasmuch as an effective amount of NO was provided to the patient for inhalation.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-9, and 11-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Kristen C. Matter/
Examiner, Art Unit 3771